FEB 12 2014

510(k) SUMMARY

510(k) Notification K131454

GENERAL INFORMATION

Applicant:
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U.S.A.
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Contact Person:
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Date 510(k) Summary Prepared: February 10, 2014

DEVICE INFORMATION

Trade Name:
Klassic HD™ Extended Offset Femoral Head

Generic/Common Name:
Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis

Classification:
21CFR§888.3358, Class II

Product Code:
LPH, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented Prosthesis
MBL, prosthesis, hip, semi-constrained, uncemented, metal/polymer, porous
LWJ, prosthesis, hip, semi-constrained, metal/polymer, uncemented

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PREDICATE DEVICE(S)

- Total Joint Orthopedics Klassic HD™ Hip System (K100445)
- Accolade II Femoral Hip Stem, Howmedica Osteonics, Corp. (K103479)
- Alloclassic Zweymuller SL Offset Femoral Stem, Centerpulse Orthopedics (K033664)
- Modular Femoral Head with Offset Trunion, Kirschner Medical Corp (K914675)

INDICATIONS FOR USE

The Klassic HD™ Extended Offset Femoral Head for use within the Klassic HD™ Hip System is intended for prosthetic replacement without bone cement in treatment of the following:

- Patient conditions of non-inflammatory degenerative joint disease (NIDJD): avascular necrosis, osteoarthritis, ankylosis, protrusio acetabuli and painful hip dysplasia.
- Patient conditions of inflammatory joint disease (IJD): rheumatoid arthritis.
- Those patients with failed previous surgery where pain, deformity or dysfunction persists.
- Revision of a previously failed hip arthroplasty.
- Patients who require a total hip replacement.

PRODUCT DESCRIPTION

The Klassic™ HD Extended Offset Femoral Head is a modular component to be used within the Klassic HD™ Hip System (K100445). The Klassic HD™ Extended Offset Femoral Head is to be used within the System as an optional prosthesis to the Klassic HD™ Femoral Head, a modular femoral head used within the Klassic HD™ Hip System. The Klassic HD™ Extended Offset Femoral Head features an offset bore and is composed of cobalt chromium and available in 32mm or 36mm diameters and available in -3.5mm, neutral, +3.5mm and +7mm head lengths. The Klassic HD™ Extended Offset Femoral Head is to be used within the hip joint replacement system as a prosthesis designed to help surgeons restore hip joint biomechanics intraoperatively by independently addressing leg length and offset.

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TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the Klassic HD™ Extended Offset Femoral Head are similar to the predicate devices in material, design and function. The Klassic HD™ Extended Offset Femoral Head assembled with a modular femoral stem functions as a femoral component intended for total hip replacement. The device utilizes a functional neck angle and lateral offset which is substantially equivalent to the end geometry achieved by the modular femoral components of predicate devices. Performance data for fatigue testing of the assembled femoral component, modular disassembly properties and range of motion were provided to support the determination of substantial equivalence.

SUBSTANTIAL EQUIVALENCE

The proposed indications for use for the Klassic HD™ Extended Offset Femoral Head are substantially equivalent to the indications for use for the predicate devices. Any differences in the technological characteristics between the devices do not raise any new issues of safety or effectiveness. Thus, the Klassic HD™ Extended Offset Femoral Head is substantially equivalent to the predicate device.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary bench testing was conducted on the Klassic HD™ Extended Offset Femoral Head to support a determination of substantial equivalence to the predicate devices.

Nonclinical Testing Summary:

The nonclinical, bench testing included:

- Fatigue Testing
- Disassembly Testing
- Range of Motion
- Biocompatibility
- Sterilization and cleaning validations
- Packaging and shelf life

The collective results of the nonclinical testing demonstrate that the materials chosen, the manufacturing processes, and design of the Klassic HD™ Extended Offset Femoral Head meet the established specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that the Klassic HD™ Extended Offset Femoral

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Head does not raise new questions of safety or effectiveness for total hip joint replacement when compared to the predicate devices.

CONCLUSION

The results of the non-clinical testing verify that the Klassic HD™ Extended Offset Femoral Head functions as intended and exhibits the appropriate characteristics for total hip joint replacement. The Klassic HD™ Extended Offset Femoral Head has the same intended use and similar technological characteristics as those of the predicate devices. Furthermore, device safety and performance testing have demonstrated that the device performs as intended in its intended use environment. As such, the Klassic HD™ Extended Offset Femoral Head is substantially equivalent to the predicate devices in terms of technological characteristics, intended use and performance.

SUMMARY

The Klassic HD™ Extended Offset Femoral Head is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 12, 2014

Total Joint Orthopedics, Incorporated
Ms. Jean Marie Wheeler
Product Development Engineer
1567 East Stratford Avenue
Salt Lake City, Utah 84106

Re: K131454
Trade/Device Name: Klassic HD™ Extended Offset Femoral Head
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, MBL, LWJ
Dated: January 10, 2014
Received: January 13, 2014

Dear Ms. Wheeler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K131454

Device Name: Klassic HD™ Extended Offset Femoral Head

Indications For Use:

The Klassic HD™ Extended Offset Femoral Head, for use within the Klassic HD™ Hip System, is intended for prosthetic replacement without bone cement in treatment of the following:

- Patient conditions of non-inflammatory degenerative joint disease (NIDJD): avascular necrosis, osteoarthritis, ankylosis, protrusio acetabuli and painful hip dysplasia.
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- Patients who require a total hip replacement.

Prescription Use _X_ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use _____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth D. Frank -S

Divison of Orthopedic Devices